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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,910	07/03/2001	Stephan Erbel	SCHWP0145US	9595

7590 01/13/2004

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EXAMINER	
CHURCH, CRAIG E	
ART UNIT	**PAPER NUMBER**
2882	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,910	ERBEL ET AL.	
	Examiner	Art Unit	
	Craig E. Church	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11 and 16-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9 and 11* is/are allowed.

6)☒ Claim(s) *16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The following is a quotation of 35 U.S.C. 103 which forms the ba i for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention i not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter a a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which aid subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifi s a prior art only under subsection (f) or (g) of section 102 of thi titl , shall not preclude patentability under this section wher th subject matter and the claimed invention were, at the time th invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 16-23, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103 a being unpatentable over Swerdloff (5661773) in view of applicant' admission of prior art. Swerdloff teaches a radiotherapy m th d comprising

acquiring CT images of a region to be treated

creating a treatment plan based on said images

treating the patient

acquiring new CT images

altering the previous treatment plan based on the new images. See, for example, lines 46-61 of column 3, Applicant's disclo ur reveals that inverse planning was known at the time of the invention, and It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the Swerdloff method for any type of therapy plan including inverse planning since it is not limit d by the Swerdloff teaching. Swerdloff does not teach recording his m th d as a computer program, but it would have been obvious to do so in ord r to increase speed and accuracy of the process.

Claims 24 and 25 are rejected under 35 U.S.C. 103 as being unpatentable over Swerdloff in view of WO 97/40766 cited by applicant. Precise patient positioning is essential in radiotherapy, and it would have been obvious therefor to one of ordinary skill in the art at th tim the invention was made to employ the WIPO system in the Swerdloff method.

Claims 9 and 11 are allowed.

Claims 26, 27 and 30 are objected to as being dependent up n a rejected base claim, but w uld be allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed October 15, 2003 have been fully considered but they are not deemed to be persuasive. Lines 45-61 of column 6 of Swerdloff referrred to by applicant on page 7 of th amendment discuss a tomographic image acquired *before treatment* to assist in setup, and applicant concludes that the CT image taken after the treatment is also used only for "setup". BUT THIS IS NOT WHAT THE PATENT SAYS, AND IT IS A GROSS MISREPRESENTATION OF THE SWERDLOFF TEACHING. Lines 51-60 of column 3 of Swerdloff explicily xplain:

> Yet another object of the invention is to provide an interfac that can be used to observe radiation delivered during a th rapy session which can be used to alter radiation doses during lat r therapy sessions. By identifying the radiation entering and exiting a patient along each ray of a beam the radiation absorbed along each ray from each gantry angle can be identified and a p t-treatment tomographic image associated with the patient lice can be provided. *The human interface of the present invention can be used to observe the post-treatment tomographic imag and compare the post-treatment image to the desired dose map to identify treatment errors. Where a treatment error (ie. over or under radiation) has occurred, the error can be noted using th human interface and can be used to alter desired dose maps during later th rapy sessions to comp nsat for th rrors.*

The post-treatment CT image (which depicts the size and locati n f internal organs) is compared to the desired dose map to identify treatment errors and to correct dose maps used in later therapy sessions. This is precisely applicant's technique and has nothing whatrever to do with pretreatment setup as fanticised by applicat.

While it is true that radiation is detected during the thearpy session, this data is a measure of the actual dose received by the patient and does not comprise image data. In fact, radiation used for therapy is of very high energy (typically greater than 500 Kev) and thu is not suitable for forming tomographic images (which typically requir around 45 Kev). That there are two different sets of information b ing acquired, one during treatment and one after treatment, is evidenced by the fact that they are compared with one another as described in th section quoted above. Furthermore, tomographic imaging requires a radiation beam with a fixed geometry, usually a fan beam, whil th beam used for therapy has a shape and size that are varied with tim and/or gantry angle as a function of the shape and location of h althy and tum rou organs by th multil af comp n ator 22 a pr scrib d by

the treatment plan. Swerdloff's therapy beam could not be employ d to form a tomographic image as asserted by applicant because it is constantly changing.

Applicant's position that "Instead it is assumed that error will occur and Swerdloff seeks to correct these errors by building a completely new plan" clearly misrepresents the Swerdloff teaching quoted above. Except for the particular type of therapy plan, thi is precisely what applicant is claiming. Applicant's disclosure reveals that inverse planning was known at the time of the invention, and It would have been obvious to one of ordinary skill in the art at the tim the invention was made to employ the Swerdloff method for any typ of therapy plan including inverse planning since it is not limited by th Swerdloff teaching.

That Swerdloff's amended plan may be based in part on do errors in the original plan discovered during treatment is not precluded by applicant's claim language. The claims do not mention error , and nothing in the instant claims precludes an intermediate step of actually performing treatment a argued. In fact the applicant' di cl sur

explains that his new plan succeeds treatment and that his new plan results from dose errors as well as from positioning errors. Page 3 of the specification states "the interior of the patient can shift between the different *treatment appointments*", and page 4 states "In an advantageous embodiment, the *dosage distribution* of an old r, conventionally or inversely produced radiotherapy plan which was found to be "OK" is used as a preset value for the recalculation".

THIS ACTION IS MADE FINAL. Applicant is reminded f the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action i set to expire THREE MONTHS from the mailing date of thi action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action i not mailed until after the end of the THREE-MONTH short n d statutory period, then the shortened statutory period will xpire on the date the advisory action is mailed, and any extensi n f pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will th statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be direct d to Examiner Church at telephone number (703) 308-4861.

Craig E. Church

Craig E. Church
Primary Examiner